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EXAMINER	
RAY HENLEY	
ART UNIT	PAPER NUMBER
1205	#10

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) RAY Henley (ex'r) (3) Ann-Sofie Sternås

(2) Richard Sterner (4) Jan Trofast

Date of interview 17 August 1994

Type: ☐ Telephonic ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☒ Yes ☐ No. If yes, brief description: brief summary of ASTHMA treatments including the invention

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.

Claims discussed: all - generally

Identification of prior art discussed: all

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: rejection discussed, but nothing could be agreed upon. The Examiner would, however, consider data relating to the ~~Fda~~ side effect profile of budesonide in an additional after-final response.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

Unless the paragraphs below have been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1–7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

☐ Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action.

Examiner's Signature

PTOL-413 (REV. 1-84)

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1. (amended) A medicament containing as active ingredients formoterol, or a physiologically acceptable salt or solvate thereof, and budesonide for inhalation treatment of respiratory disorders, and wherein said active ingredients may be delivered simultaneously or sequentially.

2. (amended) A pharmaceutical composition for administration by inhalation for treatment of respiratory disorders which composition comprises effective amounts of formoterol, or a physiologically acceptable salt or solvate thereof, and budesonide.

3. (amended) A pharmaceutical composition comprising effective amounts of formoterol, or a physiologically acceptable salt or solvate thereof, and budesonide in combination for administration by inhalation for treatment of respiratory disorders.

5. (amended) A method for the treatment of respiratory disorders which employs an effective amount of formoterol, or a physiologically acceptable salt or solvate thereof, for combination therapy and wherein formoterol and budesonide are simultaneously or sequentially administered by inhalation to a host in need of said treatment.

6. (amended) A method for the treatment of respiratory disorders which employs an effective amount of budesonide for combination therapy and wherein formoterol, or a physiologically acceptable salt or solvate thereof, and budesonide are simultaneously or sequentially administered by inhalation to a host in need of said treatment.

7. (amended) A method for the treatment of respiratory disorders which employs effective amounts of formoterol, or a physiologically acceptable salt or solvate thereof, and budesonide for combination therapy and whereby the formoterol and budesonide are administered by inhalation simultaneously or sequentially.

8. A medicament containing as active ingredients formoterol, and a physiologically acceptable salt or solvate thereof, and budesonide for inhalation treatment of respiratory disorders, and wherein said active ingredients may be delivered simultaneously or sequentially.

9. A pharmaceutical composition for administration by inhalation for treatment of respiratory disorders, which composition comprises formoterol, and a physiologically acceptable salt or solvate thereof, and budesonide.

10. A pharmaceutical composition which comprises effective amounts of formoterol, and a physiologically acceptable salt or solvate thereof, and budesonide in combination for

administration by inhalation for treatment of respiratory disorders.

11. A method for the treatment of respiratory disorders which employs an effective amount of formoterol, and a physiologically acceptable salt or solvate thereof, for combination therapy and wherein formoterol and budesonide are simultaneously or sequentially administered by inhalation to a host in need of said treatment.

12. A method for the treatment of respiratory disorders which employs an effective amount of budesonide for combination therapy and wherein formoterol, and a physiologically acceptable salt or solvate thereof, and budesonide are simultaneously or sequentially administered by inhalation to a host in need of said treatment.

13. A method for the treatment of respiratory disorders which employs effective amounts of formoterol, and a physiologically acceptable salt or solvate thereof, and budesonide for combination therapy and whereby the formoterol and budesonide are administered by inhalationn simultaneously or sequentially.

1. (twice amended) A medicament containing as active ingredients a physiologically acceptable salt of formoterol[, or a physiologically acceptable salt] or a solvate thereof, and budesonide for inhalation treatment of respiratory disorders[, and wherein said active ingredients may be delivered simultaneously or sequentially].

2. (twice amended) A pharmaceutical composition [for administration by inhalation for treatment of respiratory disorders] which composition comprises effective amounts of a physiologically acceptable salt of formoterol[, or a physiologically acceptable salt] or a solvate thereof, and budesonide, together with a pharmaceutically acceptable carrier, for inhalation treatment of respiratory disorders.

7. (twice amended) A method for the treatment of respiratory disorders which employs effective amounts of a physiologically acceptable salt of formoterol[, or a physiologically acceptable salt] or a solvate thereof, and budesonide [for combination therapy and] whereby [formoterol and budesonide are simultaneously or sequentially] the active ingredients are administered by inhalation to a host in need of said treatment.

--14. A method according to claim 7, whereby the effective amount the physiologically acceptable salt of formoterol or solvate thereof is 6-100 μg per day and the effective amount of budesonide is 50-4800 μg per day.

15. The method according to claim 14 wherein the effective amount of the physiologically acceptable salt of formoterol or solvate thereof is 6-48 μg per day and the effective amount of budesonide is 100-1600 μg per day.

16. The method according to claim 7, whereby the administration is performed from a dry powder inhaler.

17. The method according to claim 7, whereby the administration is performed from a metered dose inhaler.--